Advanced Brain Monitoring, Inc. Sleep Profiler

510(k) Summary K120450

In accordance with 21 CFR 807.92 the following summary of information is provided: SEP 19 2012

DATE: September 6, 2012

SUBMITTER:

Advanced Brain Monitoring
2237 Faraday Avenue, Suite 100
Carlsbad, CA 92008
T 760.720.0099
F 760.720.3337

PRIMARY CONTACT PERSON:

Adrienne Lenz, RAC
Founder
Pathway Regulatory Consulting, LLC
T 262-290-0023

SECONDARY CONTACT PERSON:

Dan Levendowski
President and Co-founder
Advanced Brain Monitoring, Inc.

DEVICE:

TRADE NAME: Sleep Profiler

COMMON/USUAL NAME: automatic event detection software for polysomnograph with electroencephalograph

CLASSIFICATION NAMES: 882.1400 Electroencephalograph

PRODUCT CODE: OLZ

PREDICATE DEVICE(S):

K112514 Apnea Risk Evaluation System (ARES), Model 610

K112102 MICHELE Sleep Scoring System

Advanced Brain Monitoring, Inc. Sleep Profiler

DEVICE DESCRIPTION:

The Sleep Profiler is a software application that analyzes previously recorded physiological signals obtained during sleep. The Sleep Profiler software can analyze any EDF files meeting defined specifications, including signals acquired with the Advanced Brain Monitoring X4 System which is the subject of a separate 510(k).

Automated algorithms are applied to the raw signals in order to derive additional signals and interpret the raw and derived signal information. The software automates recognition of: a) sleep stage, b) snoring frequency and severity, c) pulse rate, d) cortical (EEG), sympathetic (pulse) and behavioral (actigraphy and snoring) arousals. A single channel of electrocardiography, electrooculargraphy, electromyography, or electroencephalography can be optionally presented for visual inspection and interpretation. The software identifies and rejects periods with poor electroencephalography signal quality. The full disclosure recording of derived signals and automated analyses can be visually inspected and edited prior to the results being integrated into a sleep study report.

Medical and history information can be input from a questionnaire. Responses are analyzed to provide a pre-test probability of Obstructive Sleep Apnea (OSA) (a condition that cannot be diagnosed with Sleep Profiler) so an appropriate referral to a sleep physician is made. The automated analyses of physiological data are integrated with the questionnaire data, medical and history information to provide a comprehensive report. Several report formats are available depending on whether the user has acquired more than one night of data, wishes to obtain a narrative summary report or provide patient reports.

INTENDED USE:

Sleep Profiler is intended for the diagnostic evaluation by a physician to assess sleep quality in adults only. The Sleep Profiler is a software-only device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals and snoring.

TECHNOLOGY:

The Sleep Profiler software is similar to software in the ARES Model 610 and MICHELE Sleep Scoring System. The following table highlights similarities and differences in technology.

Specification	Sleep Profiler	ARES Model 610 (K112514)	MICHELE Sleep Scoring System (K112102)	Discussion Differences
Indications for Use	Sleep Profiler is intended for the diagnostic evaluation by a physician to assess sleep quality in adults only. The Sleep Profiler is a software-only device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals and snoring.	The Apnea Risk Evaluation System (ARES) is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home diagnosis of adults with possible sleep-related breathing disorders.	The MICHELE Sleep Scoring System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory related sleep disorders. The MICHELE Sleep Scoring System is intended to be used for analysis (automatic scoring and manual restoring), display, redisplay (retrieve), summarizing, reports generation and networking of digital data collected by monitoring devices typically used to evaluate sleep and respiratory related sleep disorders. The device is to be used under the supervision of a physician. Use is restricted to files obtained from adult patients.	Equivalent. The Sleep Profiler is a software application applied to previously acquired data which is similar to MICHELE. The ARES includes both data acquisition and analyses, and is cleared to detect sleep vs. wake and REM vs. Non-REM. Sleep Profiler, MICHELE and ARES have the same intended diagnostic effect in staging sleep. The Sleep Profiler's indication is a subset of the ARES and MICHELE as it does not analyze respiratory data.

Specification	Sleep Profiler	ARES Model 610 (K112514)	MICHELE Sleep Scoring System (K112102)	Discussion Differences
Derived Signals	• Sleep stages Rapid Eye Movement (REM) and nREM (N1, N2, N3) • Pulse rate • Snoring loudness • Sleep/wake • Head movement and position • Snoring, sympathetic, behavioral and cortical arousals • ECG,EOG, EMG waveform	• Sleep stages Rapid Eye Movement (REM) and nREM • Pulse rate • Snoring loudness • Sleep/wake • Head movement and position • Snoring, sympathetic, behavioral arousals • SpO_2 • Airflow • Respiratory Effort (Optional) • Apneas and Hypopneas	• Sleep stages Rapid Eye Movement (REM) and nREM (N1, N2, N3) and wake • Arousals • Periodic Leg Movements • Apneas and Hypopneas	Equivalent. Sleep Profiler processes raw data, applies filters, derives a subset of signals, and applies an analysis to those signals like ARES. Display of ECG/EOG/EMG is similar to display of the other waveforms; no analysis of these waveforms are performed. Unlike ARES, Sleep Profiler does not measure SpO2, airflow or respiratory effort, or detect Apneas/Hypopneas.
Reports	• Single night graphic and patient Hx • Two night comparison table	• Single night graphic, narrative and patient Hx • Two night comparison table	Not specified	Equivalent. Both ARES and Sleep Profiler reports provide sleep time, sleep efficiency, sleep/wake, medical history and disease management comments. The ARES report identifies statistics and presents graphs relevant to sleep apnea whereas the Sleep Profiler report identifies statistics and presents graphs related to sleep staging.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF NON-CLINICAL TESTS:

The following quality assurance measures were applied to the development of the Sleep Profiler Software:

- Risk Analysis
- Software Validation

SUMMARY OF CLINICAL TESTS:

The Sleep Profiler software has been the subject of clinical testing which validates the sleep staging algorithms by comparison to sleep staging made by manual observation by three raters who were either sleep technicians or physicians. There were 44 subjects. The results are presented in the table below:

		Epochs assigned by Sleep Profiler						% agreement	
	Overall	Wake	N1	N2	N3	REM	Total	Positive	Negative
Epochs assigned by Expert Scoring	Wake	6730	921	557	27	296	8531	0.79	0.95
	N1	807	1962	1652	40	493	4954	0.40	0.91
	N2	348	1426	11848	958	218	14798	0.80	0.83
	N3	36	24	1194	3928	8	5190	0.76	0.97
	REM	178	530	681	35	3641	5065	0.72	0.97
	No-Consensus	124	91	324	67	47	653		
	Total	8223	4954	16256	5055	4703	39191		

The positive and negative percent agreement obtained during clinical validation of the Sleep Profiler are similar to that obtained by the predicate device, MICHELE (K112102), which was validated using a different data set. The published results from their study are reported below.

SCORING FUNCTION	MICHELE				
	Total by Techs.	APPA	ANPA	Overall % Agreement	kappa (%)
SLEEP STAGING	24967			82.6	76.5
Awake	6563	89.9	96.4		
N1	2411	50.4	94.7		
N2	9846	82.9	89.6		
N3	2862	82.9	97.5		
Rem	3285	89.8	98.5		
No Consensus	283				

CONCLUSION:

Advanced Brain Monitoring considers the Sleep Profiler software to be as safe, as effective, and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 19 2012

Advanced Brain Monitoring
c/o Mr. Daniel J. Levendowski
President and Co-Founder
2237 Faraday Avenue, Suite 100
Carlsbad, CA 92008

Re: K120450
Trade/Device Name: Sleep Profiler
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: September 6, 2012
Received: September 10, 2012

Dear Mr. Levendowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tessia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Advanced Brain Monitoring, Inc. Sleep Profiler

510(k) Number (if known): K120450

Device Name: Sleep Profiler

Indications for Use:

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Prescription Use_X___ AND/OR Over-The-Counter Use__

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Q. Hoang

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120450